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Paper 61
Filed: 24 February 2009

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Yeda Research and Development Co. Ltd.,
Junior Party
(Patent 7,108,999,
Inventors: David Wallach, Mark Boldin,
Eugene Varfolomeev and Igor Mett),

v.

The Regents of the University of Michigan,
Senior Party
(Application 08/443,982
Inventors: Vishva M. Dixit and
Karen O'Rourke).

Patent Interference 105,545 (RES)
(Technology Center 1600)

SCHAFER, *Administrative Patent Judge.*

Decision - Motions - Bd.R. 125(a)

- 1 Michigan proposed an amendment narrowing and canceling some of
- 2 its involved claims. Paper 58. The amendment was authorized (Paper 59)
- 3 and Michigan filed the amendment in its involved application (Paper 60).

1 Based upon the amended claims, the parties jointly move that there is no
2 interference-in-fact between Michigan's amended claims and any of Yeda's
3 claims. Paper 45. The parties' motion for no interference-in-fact is granted.

4 The parties' claims relate to certain proteins which bind the
5 intracellular domain of the FAS cell receptor. The FAS receptor is a death
6 receptor involved in apoptosis or cellular death related pathways. Binding
7 of these proteins to the intracellular domain of the FAS receptor modulates
8 or mediates the cellular function of a FAS receptor.

9 Findings of Fact

10 The Claimed Subject Matter

11 F. 1. The parties' claims define their inventions in terms of specific amino
12 acid sequences.

13 F. 2. Yeda's protein (its Seq. ID No:2) is 256 amino acids in length. Paper
14 15, p. 7.

15 F. 3. Michigan's protein (coincidentally also designated Seq. ID No:2) is
16 208 amino acids in length. Paper 12, p. 5.

17 F. 4. The two sequences differ in two respects: (1) Yeda's initial 48 amino
18 acid leader sequence is not specifically recited in Michigan's sequence
19 (Ex. 1009, ¶ 23) and (2) the amino acid at position 80 of Yeda's sequence
20 and the corresponding amino acid at position 32 of Michigan's sequence
21 are different (Ex. 1009, ¶ 27).

22 F. 5. At the corresponding positions Yeda's protein has Valine while
23 Michigan's sequence has Glycine. Ex. 1009, ¶ 28.

24 F. 6. Yeda's claims do not describe the subject matter of Michigan's claims
25 and vice versa.

1 **Obviousness**

- 2 F. 7. There are nearly 5000 potential single residue substitutions that could
3 be made to Yeda's protein (256 residues x 19 amino acids). Ex. 1009, ¶
4 43.
- 5 F. 8. The literature includes many examples illustrating that the
6 Glycine/Valine substitution effects protein function. Ex. 1009, ¶¶ 57 –
7 59; Exs. 1004–1008.
- 8 F. 9. The substitution of Glycine for Valine and vice versa is known to
9 have a significant potential to adversely affect polypeptide function. Ex.
10 1009, ¶ 48.
- 11 F. 10. With respect to intracellular proteins the substitution of
12 Glycine/Valine substitution is disfavored. Ex. 1009, ¶¶ 52, 53 and 54;
13 Ex. 1011, pp. 5 and 8.
- 14 F. 11. One having ordinary skill in the art would have avoided the
15 Glycine/Valine substitution. Ex. 1009, ¶ 56.
- 16 F. 12. The effect on the properties of Michigan's and Yeda's proteins by the
17 substitution of Valine for Glycine and vice versa at position 32 and 80
18 respectively is highly unpredictable. Ex. 1009, ¶¶ 42; 60-61.
- 19 F. 13. There is no reasonable expectation of success that the Glycine/Valine
20 substitution at position 32 of Michigan's protein or at position 80 of
21 Yeda's protein would result in protein that would modulate or mediate
22 the cellular function of a FAS receptor. Ex. 1009, ¶ 46.
- 23 F. 14. Dr. Chinnaiyan, the parties' expert, testifies that he is not aware of
24 literature or prior art that predicts the impact of the substitution of Valine
25 and Glycine on the structure of the proteins. Ex. 1009, ¶ 40.
- 26 F. 15. Dr. Chinnaiyan testifies that he is unaware of any reason to change the
27 specific amino acid at position 32 of Michigan's protein to Valine or

suggests changing the amino acid at position 80 of Yeda's protein. Ex. 1009, ¶ 41.

Issue

Have the parties demonstrated that the Glycine/Valine substitution at position 80 of Yeda's protein or position 32 of Michigan's protein would have been unobvious?

Principals of Law

"An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 37 C.F.R. § 41.203.

Obviousness of a chemical compound over a similar compound requires some reason to modify the prior art compound. *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007).

Analysis

Both parties' claims include a reference to specific protein sequences. There are two differences between the respective sequences. The first, and mostly insignificant, is the difference in length of the sequences. Yeda's is 256 amino acids long and Michigan's is 208. Paper 12, p. 5; Paper 15, p. 7. Yeda's protein includes a 48 amino acid leader sequence not included in Michigan's protein. Ex. 1009, ¶ 23. The parties do not argue that the presence or absence of the leader sequence patentably distinguishes the two proteins.

The other difference, which is the focus of the motion, resides in a different amino acid at a corresponding location in each protein. Yeda's protein has Valine at position 80 while Michigan's sequence has Glycine at corresponding position 32. Ex. 1009, ¶ 28.

1 In the parties view, regardless of which sequence is taken as presumed
2 prior art, it would not have been obvious to substitute one amino acid for the
3 other at the specific location. Paper 45, p. 7.

4 To support their position, the parties rely on the testimony of Dr.
5 Chinnaiyan. Dr. Chinnaiyan is qualified as an expert in the subject matter
6 Ex. 1009, ¶¶ 1-6. Dr. Chinnaiyan testimony is credited.

7 Dr. Chinnaiyan testifies that he is unaware of any reason why one
8 skilled in the art would choose to change the amino acid at position 80 of
9 Yeda's protein or position 32 of Michigan's protein. Ex. 1009, ¶ 41. Thus a
10 person skilled in the art would need to pick for example, the appropriate
11 amino acid residue to change out of 256 possible choices in Yeda's protein
12 and then choose Glycine out of 19 other possible amino acid choices. In
13 other words, a person skilled in the art would have to make the right choice
14 out of almost 5000 possible modifications. Ex. 1009, ¶ 43.

15 Additionally, the record establishes that Glycine/Valine substitution is
16 known to effect protein properties and that the substitution has a significant
17 potential to have an adverse effect. Ex. 1009, ¶¶ 48 and 57-59; Ex. 1004-
18 1008. The effect of the Glycine/Valine substitution on the properties of the
19 protein is unpredictable. Ex. 1009, ¶¶ 42 and 60-61. There record also
20 establishes that a person of ordinary skill in the art would not have a
21 reasonable expectation that the Glycine/Valine substitution would result in a
22 protein that would modulate or mediate the cellular function of the FAS
23 protein. Ex. 1009, ¶ 46. Additionally, with respect to intracellular proteins,
24 the Glycine/Valine substitution is a disfavored change. Ex. 1009, ¶¶ 52-54.

25 It appears, therefore, that the person having ordinary skill would not
26 have a reason to modify either of the two proteins by the Glycine/Valine
27 substitution. Obviousness of a chemical compound requires some reason to

1 modify the prior art compound. *Takeda Chem.*, 492 F.3d at 1356. The
2 record here establishes by a preponderance of the evidence that one skilled
3 in the art would have reason not to modify the proteins by substituting
4 Valine for Glycine and vice versa at the parties' respective positions 80 and
5 32. The parties have established that this substitution of Valine for Glycine
6 and vice versa in the parties' proteins would not have been obvious.

7 Accordingly, an interference does not exist between Yeda's claims
8 and Michigan's amended claims. 37 C.F.R. § 41.203.

9 The parties' joint motion is granted.

10 **ORDER**

11 It is

12 **ORDERED** that the parties' joint motion for no interference-in-fact is
13 granted;

14 **FURTHER ORDERED** that Yeda's involved claims do not interfere
15 with Michigan's Claims 61, 72, 73, and 76-78 as shown in Paper 60;

16 **FURTHER ORDERED** that Michigan's Claims 61, 72, 73, and 76-
17 78 (Paper 60) do not interfere with Yeda's involved claims; and

18 **FURTHER ORDERED** that a copy of Michigan's amended claims
19 (Paper 60) be attached to and is part of this opinion.

20

/Richard E. Schafer/
Administrative Patent Judge

cc (electronic delivery):

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